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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT	PAPER NUMBER
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3736

NOTIFICATION DATE	DELIVERY MODE
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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/552,366	Applicant(s) JADIDI, FARAMARZ	
	Examiner Brian Szmaj	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52 and 56-83 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52 and 56-83 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 October 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Objections

1. Claim 52 is objected to because of the following informalities: In line 4, "signal" appears it should be spelled as "signals". Appropriate correction is required.
2. Claim 68 is objected to because of the following informalities: "said a muscle activity monitor" appears it should read as "a muscle activity monitor". Appropriate correction is required.
3. Claim 72 is objected to because of the following informalities: "earlier" should read as "earlier.". Appropriate correction is required.
4. Claim 83 is objected to because of the following informalities: "the second and third harmonic frequencies" should read a "a second and third harmonic frequencies". Appropriate correction is required.

Drawings

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the combination of a microphone, vibration sensor and/or other sensors, in conjunction with EMG electrodes, per Claim 62 in combination with Claim 52, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure

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number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 52 and 62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 52 discloses a "signal provider", and further discloses the use of electrodes to detect muscle activity. Claim 62 however discloses the "signal provider" comprises a "microphone, a sensor for sensing vibrations and/or other sensor means".

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The current specification fails to support an apparatus using both "a microphone, a sensor for sensing vibrations and/or other sensing means" in combination with electrodes for sensing muscle activity.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 52, 61, 68 and 74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claim 52, the current claim discloses both "a signal provider configured to provide signal indicative of muscle activity", and measuring normally occurring muscle activity and a maximal muscle activity using electrodes. Based on the current specification, the "signal provider" includes a microphone, vibration sensor, or other sensing means. Based on the current claim language, it is unclear to the Examiner if the claimed "signal provider" encompasses a microphone, vibration sensor, or other sensing means, since the claim language has not limited the claimed "signal provider" to only electrodes for providing signals indicative of muscle activity.

10. Regarding Claim 61, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and

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then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 61 recites the broad recitation “configured to test said electrodes”, and the claim also recites “and in particular the connectivity to the user” which is the narrower statement of the range/limitation.

Regarding Claim 68, lines 10-11, “registering said muscle activity in said a muscle activity monitor measured by said electrodes” is indefinite, since it is unclear to the Examiner what is occurring in this method step. It is unclear if the muscle activity is registered in the muscle activity monitor, or if the muscle activity monitor is measured by the electrodes. Furthermore, “said muscle activity” renders the claim indefinite because it is unclear to the Examiner what muscle activity is being referred to in the claim. The claim first discloses “muscle activity” in line 3 of the claim, and then discloses in lines 7-8, “normally occurring muscle activity” and “maximal muscle activity”.

Regarding Claim 74, “an essentially maximal jaw clenching” is indefinite because it is unclear what “essentially” entails in the claim. The term “essentially” is defined as “in or by its very nature”; in essence. The term “essentially” renders the claim indefinite because the term does not clearly limit the use of a maximal jaw clenching for

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measuring the maximal muscle activity. The term "essentially" should be cancelled from the claim.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 52, 56-59, 62, 63, 65, 67-70, 72 and 76-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ober (4,669,477).

Ober discloses a means for preventing bruxism and further discloses a signal provider configured to provide signals indicative of muscle activity (20); a signal processor configured to process the signals in order to detect bruxism (26); a feedback provider configured to provide a feedback signal (16, 48); wherein the apparatus is configured for operation in a set-up mode and a use-mode (Column 3, lines 8-12, indicate the threshold can be adjusted via threshold control 32 to provide a desired predetermined level of jaw activity; this also indicates the device is setup prior to actual use); wherein the device is configured to be individually adaptable in the set-up mode, wherein a normally occurring muscle activity and a maximal muscle activity are separately measurable via electrodes that are communicable with the apparatus and mountable on selected muscles, and wherein the apparatus is configured to register and calculate a threshold value for outputting the feedback signal using the normally

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occurring muscle activity and the maximal muscle activity measured by the electrodes, the maximal muscle activity requiring a greater output of force than the normally occurring muscle activity, whereby criteria based on the threshold value is established for releasing the feedback signal to the user in such a manner the criteria is adapted to the user (Column 3, lines 8-12, again indicates the setup of the device for the user; each device would be individually setup to each person); the apparatus is configured to register and store (50) the signals indicative of muscle activity during a time interval; the apparatus is configured for adjusting the intensity of the feedback signal (32); the signal processor is configured for pattern recognition (26) (the signal processing circuitry would inherently include a means for recognizing the EMG pattern); one or more electrodes (20) for sensing EMG signals; the signal provider comprises other electrodes (EMG electrodes); the apparatus is configured for storing data (50) corresponding to the measured or processed signals (the recorder can be directly connected to the signal processor for recording of the data); a user module for wearing on the head (see Figure 3); a display for displaying results from a monitoring session (the recorded information is used by a physician to determine the progress of the patient; the recorded information would inherently require a display in order for the physician to read the recorded information); providing signals indicative of muscle activity (via electrodes 20); processing the signals to detect bruxism (via signal processing circuitry 26); providing feedback (via stimulator circuit 16 and electrodes 48); during a set-up mode, measuring normally occurring activity and a maximal muscle activity via electrodes mounted on selected muscles, registering the muscle activity in a muscle activity monitor, and using

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the muscle activities to calculate a threshold value for outputting the feedback signal whereby a criteria based on the threshold value is established for releasing the feedback signal to the user in such a manner that the criteria is adapted to the user (Column 3, lines 8-12, indicate the threshold can be adjusted via threshold control 32 to provide a desired predetermined level of jaw activity; this also indicates the device is setup prior to actual use and each device would be individually setup to each person); the threshold value is calculated automatically based on the EMG measurements (since the threshold value can be adjusted by a person, the threshold is calculated automatically by the person based on the acquired EMG signals); the threshold value is retrieved from a memory (the acquired signals are compared to the threshold value, therefore requiring a memory for storing the threshold value); the apparatus is configured for pattern recognition of the signals (the signal processing circuitry comprises means for pattern recognition); the signal processor is configured to determine the amplitude of the signals (the signal processing circuitry comprises means for determining the amplitude of the signal); low-pass filtering of the signals (the signal processing circuitry comprises filters, including low-pass filters); and the signal processor is configured to average and rectify the signals (the signal processing circuitry comprises rectifiers and other circuits for processing signals). See also Column 2, lines 30-68; Column 3, lines 1-29 and 60-68; and Column 4, lines 1-4.

Ober discloses the manual adjustment of the threshold via the threshold control (32), but does not disclose an automatic determination and adjustment of the threshold. The replacement of a manual operation with an automatic operation is a design

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consideration within the skill in the art. See *In re Venner*, 262 F.2d 91, 120 USPQ 192 (CCPA 1955). Therefore it would have been obvious to one of ordinary skill in the art to have the device automatically calculate and adjust the threshold value.

13. Claims 52, 56-59, 62-65, 67-70, 72, 77, 78 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinstein et al (6,270,466 B1) in view of Ober (4,669,477).

Weinstein et al disclose a means for providing biofeedback for treating bruxism and further disclose a signal provider configured to provide signals indicative of muscle activity; a signal processor configured to process the signals to detect bruxism; a feedback provider configured to provide a feedback; the apparatus is configured to register and store the signals indicative of muscle activity; the apparatus is configured for adjusting the intensity of the feedback signal; EMG electrodes; the signal provider comprises other electrodes (EMG electrodes); the apparatus is configured to store data corresponding to the measured or processed signals; a computer and means for transferring data thereto; a user module for wearing on the head (see Figure 2); a display (D, 102) for displaying results from a monitoring session; the threshold value is stored in a memory; means for determining the amplitude of the frequency content of the signals; low-pass filtering of the signals; and accumulating data of muscle activity and determining and storing the frequency pattern of the muscle activity.

Weinstein et al however do not disclose the apparatus is configured for operation in a set-up mode and a use-mode; wherein the device is configured to be individually adaptable in the set-up mode, wherein a normally occurring muscle activity and a

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maximal muscle activity are separately measurable via electrodes that are communicable with the apparatus and mountable on selected muscles, and wherein the apparatus is configured to register and calculate a threshold value for outputting the feedback signal using the normally occurring muscle activity and the maximal muscle activity measured by the electrodes, the maximal muscle activity requiring a greater output of force than the normally occurring muscle activity, whereby criteria based on the threshold value is established for releasing the feedback signal to the user in such a manner the criteria is adapted to the user; and the threshold value is calculated automatically based on EMG measurements.

Ober, as discussed above, disclose a means of treating bruxism and further discloses the apparatus is configured for operation in a set-up mode and a use-mode (Column 3, lines 8-12, indicate the threshold can be adjusted via threshold control 32 to provide a desired predetermined level of jaw activity; this also indicates the device is setup prior to actual use); wherein the device is configured to be individually adaptable in the set-up mode, wherein a normally occurring muscle activity and a maximal muscle activity are separately measurable via electrodes that are communicable with the apparatus and mountable on selected muscles, and wherein the apparatus is configured to register and calculate a threshold value for outputting the feedback signal using the normally occurring muscle activity and the maximal muscle activity measured by the electrodes, the maximal muscle activity requiring a greater output of force than the normally occurring muscle activity, whereby criteria based on the threshold value is established for releasing the feedback signal to the user in such a manner the criteria is

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adapted to the user (Column 3, lines 8-12, again indicates the setup of the device for the user; each device would be individually setup to each person); and the threshold value is calculated automatically based on EMG measurements. Column 3, lines 8-12, indicate the threshold can be adjusted via threshold control 32 to provide a desired predetermined level of jaw activity. This also indicates the device is setup prior to actual use and each device would be individually setup to each person.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Weinstein et al to include the use of a setup mode and a use mode, as per the teachings of Ober, since it would provide a means of customizing the device to individual users to prevent bruxism during sleep. It also would have been obvious to one of ordinary skill in the art to automate the manual calculation of the threshold value necessary to prevent bruxism, per the teachings of Ober. See *In re Venner*, 262 F.2d 91, 120 USPQ 192 (CCPA 1955).

14. Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weinstein et al (6,270,466 B1) and Ober (4,669,477) as applied to claim 52 above, and further in view of Junker et al (6,636,763 B1).

Weinstein et al and Ober, as discussed above, discloses a means for preventing bruxism but fail to disclose the signal provider comprises one or more electrodes for sensing EEG signals.

Junker et al disclose a brain-body actuated system and further disclose the use of acquiring EEG signals. See Column 3, lines 25-33.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Weinstein et al and Ober to include the use of EEG, since it is well known in the art that EEG signals can be used to indicate muscle movement.

15. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weinstein et al (6,270,466 B1), Ober (4,669,477) and Junker et al (6,636,763 B1) as applied to claim 60 above, and further in view of Stice (4,993,423).

Weinstein et al, Ober and Junker et al, as discussed above, disclose a means of obtaining muscle activity signals but fail to disclose the apparatus is configured to test the electrodes to determine if the electrodes are connected to the skin properly.

Stice discloses a means for differential lead impedance comparison and further discloses the apparatus is configured to test the electrodes to determine if the electrodes are connected to the skin properly. See Column 2, lines 64-66.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Weinstein et al, Ober and Junker et al to include the ability of determining if the electrodes are contacting the skin, as per the teachings of Stice, since it is well known in the art to utilize a means of determining the contact of the electrodes since it provides a means of accurately acquiring bioelectrical signals from the patient.

16. Claim 66 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weinstein et al (6,270,466 B1) and Ober (4,669,477) as applied to claim 52 above, and further in view of Sunouchi et al (5,368,043).

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Weinstein et al and Ober, as discussed above, disclose a means for preventing bruxism, but fail to disclose the apparatus comprises a slave module and a master module, the slave module being designed for wearing by a patient.

Sunouchi et al disclose a means for measuring muscle activity and further disclose the apparatus comprises a slave module and a master module, the slave module being designed for wearing by a patient (the patient unit acquires data and transmits the data to the CPU 20 for processing and display; therefore the patient unit is the slave unit and the CPU is the master unit). See Column 6, lines 65-68; and Column 9, lines 18-27.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Ober to include the use of a computer, as per the teachings of Sunouchi et al, since it would provide an external processing means to process the data and control the feedback means.

17. Claims 71, 73 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinstein et al (6,270,466 B1) and Ober (4,669,477) as applied to claim 52 above, and further in view of Lavigne et al (Sleep Bruxism: Validity of Clinical Research...1995).

Weinstein et al and Ober, as discussed above, disclose a means for acquiring EMG signals, processing the signals to determine the presence of bruxism and providing feedback based on the acquired signals and the threshold, but fail to disclose the threshold value is 20% of the maximal muscle activity; the normally occurring

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muscle activity is one or more grimaces performed by the user; and the maximal muscle activity is maximal jaw clenching performed by the user.

Lavigne et al disclose a means for monitoring for the presence of bruxism and further disclose the threshold value is 20% of the maximal muscle activity (p 548, second paragraph); the normally occurring muscle activity is one or more grimaces performed by the user (p 547, second column, second paragraph; the "rhythmic contractions" encompass a grimace); and the maximal muscle activity is maximal jaw clenching performed by the user (p. 547, second column, second paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Weinstein et al and Ober to include a threshold value of 20% of the maximal muscle activity, grimaces and maximal jaw clenching for setting up the apparatus, as per the teachings of Lavigne et al, since it would provide a computer based means for calculating the threshold value and providing a feedback to the user for preventing bruxism.

18. Claim 75 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weinstein et al (6,270,466 B1) and Ober (4,669,477) as applied to claim 52 above, and further in view of Prass (6,306,100 B1).

Weinstein et al and Ober, as discussed above, disclose a means for treating bruxism, but fail to teach the stored signals indicative of muscle activity are processed by FFT analysis.

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Prass discloses a means for neurophysiological monitoring and further disclose the stored signals indicative of muscle activity are processed by FFT analysis. See Column 37, lines 52-59.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Weinstein et al and Ober, to include the use of FFT analysis on the stored EMG signals, as per the teachings of Prass, since it would provide a means for performing frequency analysis on the acquired EMG signals.

19. Claims 76 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinstein et al (6,270,466 B1) and Ober (4,669,477) as applied to claim 52 above, and further in view of Massicotte et al (2004/0068196 A1).

Weinstein et al and Ober, as discussed above, disclose a means for treating bruxism using acquired EMG signals and providing feedback based on the acquired signals, but fail to disclose the apparatus is configured for frequency pattern recognition of the signals; and the frequency pattern recognition includes comparing the frequency content of the signals to the stored frequency pattern.

Massicotte et al disclose a means for trend detection in a monitoring signal and further disclose the apparatus is configured for frequency pattern recognition of the signals; and the frequency pattern recognition includes comparing the frequency content of the signals to the stored frequency pattern. See Paragraph 0057.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Weinstein et al and Ober to include

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the use of frequency pattern recognition and comparing the frequency content of the acquired signals to the stored signals, as per the teachings of Massicotte et al, since it would provide a computer based means to recognize specific signals indicating a bruxism event, such that the user can be provided feedback to arrest the bruxism event.

20. Claims 82 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinstein et al (6,270,466 B1) and Ober (4,669,477) as applied to claim 52 above, and further in view of Hine et al (5,877,444).

Weinstein et al and Ober, as discussed above, disclose a means for treating bruxism using acquired EMG signals and providing feedback based on the acquired signals, but fail to disclose the frequency pattern recognition includes comparing one or more harmonic frequencies of the signals to the stored frequency pattern; and the first harmonic frequency (fundamental frequency) is compared to the stored frequency pattern.

Hine et al disclose a tuner for instruments and further disclose the frequency pattern recognition includes comparing one or more harmonic frequencies of the signals to the stored frequency pattern; and the first harmonic frequency (fundamental frequency) is compared to the stored frequency pattern. See Column 2, lines 46-53.

Even though Hine et al discloses a means for tuning instruments, Hine et al demonstrates that it is well known to acquire the first harmonic frequency of a signal and compare it to a stored frequency pattern to provide a diagnosis. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Weinstein et al and Ober to include comparing the first

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harmonic frequency of the acquired signal to a stored frequency pattern, as per the teachings of Hine et al, since it would provide a means of accurately providing feedback to a user suffering from bruxism.

21. Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ober (4,669,477) as applied to claim 52 above, and further in view of Junker et al (6,636,763 B1).

Ober, as discussed above, discloses a means for preventing bruxism but fail to disclose obtaining EEG signals.

Junker et al disclose a brain-body actuated system and further disclose the use of acquiring EEG signals. See Column 3, lines 25-33.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Ober to include the use of EEG, since it is well known in the art that EEG signals can be used to indicate muscle movement.

22. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ober (4,669,477) and Junker et al (6,636,763 B1) as applied to claim 60 above, and further in view of Stice (4,993,423).

Ober and Junker et al, as discussed above, disclose a means of obtaining muscle activity signals but fail to disclose testing the electrodes to determine if the electrodes are connected to the skin properly.

Stice discloses a means for differential lead impedance comparison and further discloses testing the electrodes to determine if the electrodes are connected to the skin properly. See Column 2, lines 64-66.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Ober and Junker et al to include the ability of determining if the electrodes are contacting the skin, as per the teachings of Stice, since it is well known in the art to utilize a means of determining the contact of the electrodes since it provides a means of accurately acquiring bioelectrical signals from the patient.

23. Claims 64 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ober (4,669,477) as applied to claim 52 above, and further in view of Sunouchi et al (5,368,043).

Ober, as discussed above, disclose a means for preventing bruxism, but fail to disclose a computer and a means for transferring data thereto; and the apparatus comprises a slave module and a master module, the slave module being designed for wearing by a patient.

Sunouchi et al disclose a means for measuring muscle activity and further disclose a computer and a means for transferring data thereto; and the apparatus comprises a slave module and a master module, the slave module being designed for wearing by a patient (the patient unit acquires data and transmits the data to the CPU 20 for processing and display; therefore the patient unit is the slave unit and the CPU is the master unit). See Column 6, lines 65-68; and Column 9, lines 18-27.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Ober to include the use of a computer, as

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per the teachings of Sunouchi et al, since it would provide an external processing means to process the data and control the feedback means.

24. Claims 71, 73 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ober (4,669,477) as applied to claim 52 above, and further in view of Lavigne et al (Sleep Bruxism: Validity of Clinical Research...1995).

Ober, as discussed above, disclose a means for acquiring EMG signals, processing the signals to determine the presence of bruxism and providing feedback based on the acquired signals and the threshold, but fail to disclose the threshold value is 20% of the maximal muscle activity; the normally occurring muscle activity is one or more grimaces performed by the user; and the maximal muscle activity is maximal jaw clenching performed by the user.

Lavigne et al disclose a means for monitoring for the presence of bruxism and further disclose the threshold value is 20% of the maximal muscle activity (p 548, second paragraph); the normally occurring muscle activity is one or more grimaces performed by the user (p 547, second column, second paragraph; the "rhythmic contractions" encompass a grimace); and the maximal muscle activity is maximal jaw clenching performed by the user (p. 547, second column, second paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Ober to include a threshold value of 20% of the maximal muscle activity, grimaces and maximal jaw clenching for setting up the apparatus, as per the teachings of Lavigne et al, since it would provide a computer

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based means for calculating the threshold value and providing a feedback to the user for preventing bruxism.

25. Claim 75 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ober (4,669,477) as applied to claim 52 above, and further in view of Prass (6,306,100 B1).

Ober, as discussed above, disclose a means for treating bruxism, but fail to teach the stored signals indicative of muscle activity are processed by FFT analysis.

Prass discloses a means for neurophysiological monitoring and further disclose the stored signals indicative of muscle activity are processed by FFT analysis. See Column 37, lines 52-59.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Ober, to include the use of FFT analysis on the stored EMG signals, as per the teachings of Prass, since it would provide a means for performing frequency analysis on the acquired EMG signals.

26. Claims 76 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ober (4,669,477) as applied to claim 52 above, and further in view of Massicotte et al (2004/0068196 A1).

Ober, as discussed above, disclose a means for treating bruxism using acquired EMG signals and providing feedback based on the acquired signals, but fail to disclose frequency pattern recognition of the signals; and comparing the frequency content of the signals to the stored frequency pattern.

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Massicotte et al disclose a means for trend detection in a monitoring signal and further disclose frequency pattern recognition of the signals; and comparing the frequency content of the signals to the stored frequency pattern. See Paragraph 0057.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Ober to include the use of frequency pattern recognition and comparing the frequency content of the acquired signals to the stored signals, as per the teachings of Massicotte et al, since it would provide a computer based means to recognize specific signals indicating a bruxism event, such that the user can be provided feedback to arrest the bruxism event.

27. Claims 82 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ober (4,669,477) as applied to claim 52 above, and further in view of Hine et al (5,877,444).

Ober, as discussed above, disclose a means for treating bruxism using acquired EMG signals and providing feedback based on the acquired signals, but fail to disclose comparing one or more harmonic frequencies of the signals to the stored frequency pattern; and the first harmonic frequency (fundamental frequency) is compared to the stored frequency pattern.

Hine et al disclose a tuner for instruments and further disclose comparing one or more harmonic frequencies of the signals to the stored frequency pattern; and the first harmonic frequency (fundamental frequency) is compared to the stored frequency pattern. See Column 2, lines 46-53.

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Even though Hine et al discloses a means for tuning instruments, Hine et al demonstrates that it is well known to acquire the first harmonic frequency of a signal and compare it to a stored frequency pattern to provide a diagnosis. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Ober to include comparing the first harmonic frequency of the acquired signal to a stored frequency pattern, as per the teachings of Hine et al, since it would provide a means of accurately providing feedback to a user suffering from bruxism.

Response to Arguments

28. Applicant's arguments filed December 21, 2009 have been fully considered but they are not persuasive.

The Applicants argue Ober fails to teach the current limitations of currently amended Claims 52 and 68. In particular, Ober fails to teach a muscle monitoring apparatus to calculate a threshold value for outputting a feedback signal, based upon separately measured normally occurring muscle activity and a maximal muscle activity. While Ober utilized a person to determine and adjust the threshold of the device accordingly, one of ordinary skill in the art would have been able to recognize the replacement of a manual operation with an automatic operation is a mere design consideration within the skill in the art. The Applicants further argue Ober fails to disclose a set-up mode and a use mode. The Examiner respectfully disagrees. As noted above, Column 3, lines 8-12 disclose the adjustment of the threshold to indicate a

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desired predetermined level of jaw muscle activity. One of ordinary skill in the art would be able to clearly ascertain the threshold adjustment would be used during some sort of a setup of the device, prior to the use of the device. Otherwise, there would be no use for a threshold value control (32), since the device would be ready to use from the manufacturer. However, Ober has realized the need for an adjustment of the threshold value because each individual creates a different maximal bite force. Therefore, Ober relies upon the threshold control to adjust the device for each individual user prior to use. The Applicants further argue Ober does not teach normally occurring muscle activity and maximal muscle activity. The Examiner respectfully disagrees. As discussed above, Ober discloses setting up the device and adjusting the threshold value accordingly to each user. One of ordinary skill in the art, based on Ober's disclosure of bruxism occurring primarily during sleep, would obviously require the device to be setup to differentiate between a normal muscle activity and a maximal muscle activity. Otherwise, the device would constantly provide feedback to the user during sleep, even when bruxism is not occurring.

The Applicants then argue the combination of Weinstein et al and Ober fail to teach all of the claimed limitations. In particular, the Applicants again argue Ober fails to disclose the claimed setup mode. The Examiner respectfully disagrees. See above response to Applicants' arguments regarding Ober's lack of disclosure of the claimed setup mode.

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Since the prior art of Ober and Weinstein et al in view of Ober teach all of the claimed limitations of independent claims 52 and 68, the rejections of dependent claims 60, 61, 64, 66, 71, 73-76 and 81-83 are also being maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmál whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Brian Szmál/
Examiner, Art Unit 3736

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